

## The ABC Sleep Pilot Study Participant Information

<b>Title:</b>	ABC Sleep Pilot Study
<b>Ethics Approval Number:</b>	HREC 1403

***You are invited to participate in a pilot study to test the feasibility of using a new sleep monitoring device to examine sleep health.***

***Please read this participant information carefully.***

This information is provided to help you to decide if you would like to take part in the ABC Sleep Pilot Study, which is an additional component of the Australian Breakthrough Cancer (ABC) Study.

***If you have any questions, please contact the study team on 1800 688 419 or email [info@abcstudy.com.au](mailto:info@abcstudy.com.au).***

### **1.1 Your consent**

Participation in this research is voluntary. If you do not wish to take part, you do not have to.

If you decide you want to take part in the research project, you will be asked to provide your consent. By giving your consent, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project as described
- Consent to the use of your personal and health information as described.

If you consent to participate in this pilot study, we will provide you with hard copies of the *Participant Information* and *Consent Form* when we send the devices.

### **1.2 Who runs the ABC Study and ABC Sleep Pilot Study?**

The ABC Study is run by Cancer Council Victoria. The Chief Investigators are:

- Professor Roger Milne, Head, Cancer Epidemiology Division
- Associate Professor Brigid Lynch, Deputy Head, Cancer Epidemiology Division
- Professor Graham Giles, Distinguished Fellow, Cancer Epidemiology Division
- Prof Melissa Southey, Precision Medicine Biorepository, Monash University
- Dr Fiona Bruinsma, Senior Manager, Research Coordination, Cancer Epidemiology Division.

The researchers overseeing the ABC Sleep Pilot Study are Dr Yohannes Adama Melaku, Postdoctoral Fellow, Dr Fiona Bruinsma and Associate Professor Brigid Lynch.

The ABC Sleep Pilot Study has been approved by the Human Research Ethics Committee (HREC) of the Cancer Council Victoria. This study will be conducted according to the *National Statement on Ethical Conduct in Human Research (2007)*.

### **1.3 What is the ABC Sleep Pilot Study?**

Sleep is linked to both mental and physical health. Sleep disorders are becoming more common and are linked to an increasing prevalence of chronic diseases. Accurately measuring sleep health and collecting data from large studies has been challenging. The ABC Sleep Pilot Study will test the feasibility of using a new sleep device that is placed under the mattress of people's beds. This technology collects sleep data (including sleep duration and quality of sleep). We will also be measuring movement behaviours (physical activity, sitting, standing, reclining) using a watch-like device (accelerometer) that is worn on your wrist.

#### **1.4 Who will be taking part in the ABC Sleep Pilot Study?**

Participants in the Australian Breakthrough Cancer Study (ABC) Study are randomly selected to be invited to participate in the ABC Sleep Pilot Study.

#### **1.5 What does this Pilot study involve?**

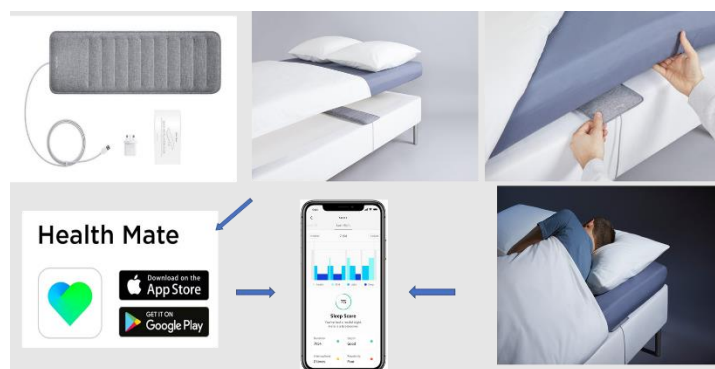
If you decide to take part in the ABC Sleep Pilot Study, you will be asked to do the following:

##### ***a. Use the under-mattress sleep device for 14 days***

You will be provided with a Withings under-mattress sleep device that records sleep data. We will ask you to put this device under your mattress for 14 days. This flat device is 19 centimetres wide, 62 centimetres long and 350 grams. It measures total sleep time, sleep quality, sleep apnoea and heart rate. You will be asked to place this sleep device under your mattress and to connect the device via Bluetooth with a mobile app (Health Mate app) downloaded onto your phone or other device. In order to use the Withings device you will need Wifi internet access.

The set-up process is as follows:

1. If you consent to participate in the ABC Sleep Pilot Study the ABC Study team will create an anonymous ('dummy') account to use when logging in to the Health Mate app. This unique dummy username and password will be sent to you by email
2. To set up the Health Mate account, assigned sex, date of birth, height and body mass must be provided. We will ask you to provide these details to us when you opt-in to participate in the Sleep Pilot Study. For date of birth we will use 01/01/year of birth so that full date of birth isn't entered into the Withings system. We will assign you a unique dummy username and password.
3. To set up the dummy Withings account we need to consent to the Withings Company Terms and Conditions and Privacy policy on your behalf. Please ensure that you have read the Withings Company Terms and conditions and Privacy Policy before consenting to participate in this pilot study. They can be accessed here: (<https://www.withings.com/fr/en/legal/privacy-policy#/fr/en/legal/services-terms-and-conditions>). Link to Withings Privacy policy (<https://www.withings.com/fr/en/legal/privacy-policy>).
4. You will be able to update your details in the Health Mate app once you are logged on. Please do not not to enter your name, address or date of birth.
5. We will ask you to link the Health Mate app with the under-mattress device in order to share the data with our research team. Your sleep data will be collected through this app and securely stored on the Withings Company systems. We will be able to access your data via the email and password we provided you.



**b. Wear the wrist-worn ActiGraph accelerometer for 14 days**

You will also be asked to simultaneously wear an accelerometer, which is similar to a wrist watch, for the same period of time (14 days). The data will be downloaded from the device when you return the device to Cancer Council Victoria and stored on Cancer Council Victoria systems.

**c. Complete an online activity monitoring daily diary for 14 days**

You will be asked to complete a brief online activity diary. A link to this diary will be sent to you through email or SMS or you can access it via the ABC Study portal using your ABC Study login and password. We will also send you a paper copy that you can use to record the data each day and then enter it online at the end of the study period. This is a very short questionnaire that is to be completed every day (preferably in the morning). The diary contains questions related to your sleep timing and sleep medication use.

**d. Complete an online questionnaire at the end of the study**

At the end of 14 days, you will be asked to complete a short online questionnaire. A link to this will be sent via email or can be accessed via the ABC Study portal. This questionnaire asks about your sleep health, stress level, exercise and timing of meals, as well as your experience in using the under-mattress sleep device.

If you agree to take part in this pilot study, we will send you a package containing:

1. A letter describing what is in the package
2. **A Withings under-mattress sleep device**
3. An **ActiGraph GT3X plus accelerometer** on a wristband
4. Instructions (with illustrations) demonstrating how to set up and place the sleep device and how to wear the accelerometer.
5. Copies of the Information Sheet and Consent Form for your records; and
6. A postage-paid satchel for you to return the devices to us after wearing the devices for 14 days.

**1.6 What other information or materials will the study collect?**

We will not collect any information about you other than that outlined in this information sheet.

**1.7 How are my privacy and confidentiality protected?**

Cancer Council Victoria is subject to privacy and health records laws which regulate how it collects and handles personal information, including sensitive and health information. Information that identifies you, such as your name, date of birth, and address will be restricted to staff employed by Cancer Council Victoria.

Written information about you will be stored in an area with access restricted to a small number of staff all of whom are required to sign confidentiality agreements. All electronic records containing personal information will be stored on a password protected computer system. These will be protected by high level security measures. For further information, please refer to the Cancer Council Victoria Privacy Statement available on Cancer Council Victoria's website.<link>

While obtaining your sleep data from Withings Company we do not provide any personally identifiable data associated with you. You will receive a unique login username and a password. If you login using these details, the Health Mate app will not contain your name or address.

Your information, that will not include your name, may be made available to other researchers, including interstate and overseas researchers, for studies consistent with the aims of the ABC Study

Government agencies and publishers of scientific journals sometimes require research data to be available via open or mediated access data repositories that meet international security and safety standards for sharing data. In such cases, no individually identifiable data would be provided.

We will not include your name or other identifying information in any publication.

In accordance with relevant Australian and Victorian privacy and other legislation, you have the right to access the information about you that has been collected and held by us. You also have the right to ask for information to be corrected.

You can read and download your sleep health report through the Health Mate app. You can also contact the study team on 1800 688 419 or email [abcstudy@cancervic.org.au](mailto:abcstudy@cancervic.org.au) if you would like to access your information from the sleep device or accelerometer. If you do so, once we verify your identity, you will be sent a brief report that summarises your sleep and/or activity data collected by the sleep device and accelerometer. We can also provide you with details of your questionnaire responses.

### **1.8 How can I find out what the researchers learn from the study?**

Participants will be sent newsletters as part of their participation in the ABC Study. Findings from the ABC Sleep Pilot Study may be included in future newsletters. Individual participants will not be identified in any articles; only aggregate response data will be discussed.

### **1.9 Are there any benefits to me?**

The Health Mate app provides a daily sleep health report, accessible to you on the app interface. This sleep health report could help you to better understand your sleep health. You may not receive any other direct benefit by participating in the ABC Sleep Pilot Study, but the results of the research could benefit others in the future. This study is designed to investigate feasibility of using an under-mattress sleep device to measure objective sleep health data in a large sample of people in order to improve the accuracy and precision of sleep health measurements.

Participation in the study should not alter your use of routine health care or health screenings in any way.

### **1.10 Are there any risks to me?**

The risk posed to participants of the ABC Sleep Pilot Study related to the collection of epidemiological data on sleep, physical activity and diet is "low". You will be asked a range of questions about your health and lifestyle that some people may find intrusive. You are only required to answer the questions that you feel comfortable in answering. Through participation

in this study, you may become aware of issues with your sleep health that you may not previously been aware of. Some participants may find these sleep health issues uncomfortable. Finding out about these issues may enable them to be addressed, with potential for improvements in sleep and/or overall health.

### **1.11 What if I change my mind about participating in the ABC Sleep Pilot Study?**

You can withdraw from the study at any time, without giving a reason, by contacting the study team on 1800 688 419 or email [abcstudy@cancervic.org.au](mailto:abcstudy@cancervic.org.au). If you do withdraw your consent during the research project, the study investigators and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be confirmed and to comply with law. Please let the study team know if you do not want us to continue using your information. If you no longer want your information to be used, they will be de-identified and/or destroyed securely. If you withdraw after analyses have been undertaken, it may not be possible to withdraw all data as it may have been accessed and used for other ethically approved studies.

### **1.12 What if I have more questions?**

If you have any questions about the ABC Sleep Pilot Study, or would like any additional information before deciding to participate, please contact the study team on 1800 688 419 or email [abcstudy@cancervic.org.au](mailto:abcstudy@cancervic.org.au).

### **1.13 What can I do if I have a complaint?**

Cancer Council Victoria's Human Research Ethics Committee has approved this study based on strict ethical standards and security of participant confidentiality and privacy. If you have any concerns about the conduct of this study, please contact the Human Research Ethics Committee, tel: (03) 9514 6200, email [rgu@cancervic.org.au](mailto:rgu@cancervic.org.au). Alternatively, contact the Office of Australian Information Commissioner at [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au) or telephone on 1300 363 992.

*Thank you for your time. If you have any questions about The ABC Sleep Pilot Study, or want to talk about taking part in it, please call the study team on: 1800 688 419 or email [abcstudy@cancervic.org.au](mailto:abcstudy@cancervic.org.au).*